# General

## Guideline Title

Diabetic foot problems: prevention and management.

## Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Diabetic foot problems: prevention and management. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Aug 26. 47 p. (NICE guideline; no. 19).

## Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Centre for Clinical Practice. Diabetic foot problems. Inpatient management of diabetic foot problems. London (UK): National Institute for Health and Clinical Excellence (NICE); 2011 Mar. 31 p. (Clinical guideline; no. 119).

This guideline meets NGC's 2013 (revised) inclusion criteria.

# Recommendations

## Major Recommendations

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the Internal Clinical Guidelines (ICG) Programme on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

The wording used in the recommendations in this guideline (for example words such as 'offer' and 'consider') denotes the certainty with which the recommendation is made (the strength of the recommendation) and is defined at the end of the "Major Recommendations" field.

Unless stated otherwise, the recommendations apply to children, young people and adults with diabetes.

Care within 24 Hours of a Person with Diabetic Foot Problems Being Admitted to Hospital, or the Detection of Diabetic Foot Problems (If the Person Is Already in Hospital)

The recommendations in this section were originally published in the NICE guideline on the inpatient management of diabetic foot problems (NICE guideline CG119), which has been replaced by this guideline.

Each hospital should have a care pathway for people with diabetic foot problems who need inpatient care. [2011]

A named consultant should be accountable for the overall care of the person, and for ensuring that healthcare professionals provide timely care.

[2011]

Refer the person to the multidisciplinary foot care service within 24 hours of the initial examination of the person's feet. Transfer the responsibility of care to a consultant member of the multidisciplinary foot care service if a diabetic foot problem is the dominant clinical factor for inpatient care. [2011]

The named consultant and the healthcare professionals from the existing team should remain accountable for the care of the person unless their care is transferred to the multidisciplinary foot care service. [2011]

Care Across All Settings

Commissioners and service providers should ensure that the following are in place:

- A foot protection service for preventing diabetic foot problems, and for treating and managing diabetic foot problems in the community.
- A multidisciplinary foot care service for managing diabetic foot problems in hospital and in the community that cannot be managed by the foot protection service. This may also be known as an interdisciplinary foot care service.
- Robust protocols and clear local pathways for the continued and integrated care of people across all settings, including emergency care and general practice. The protocols should set out the relationship between the foot protection service and the multidisciplinary foot care service.
- Regular reviews of treatment and patient outcomes, in line with the National Diabetes Foot Care Audit .

The foot protection service should be led by a podiatrist with specialist training in diabetic foot problems, and should have access to healthcare professionals with skills in the following areas:

- Diabetology
- Biomechanics and orthoses
- Wound care

The multidisciplinary foot care service should be led by a named healthcare professional, and consist of specialists with skills in the following areas:

- Diabetology
- Podiatry
- Diabetes specialist nursing
- Vascular surgery
- Microbiology
- Orthopaedic surgery
- Biomechanics and orthoses
- Interventional radiology
- Casting
- Wound care

The multidisciplinary foot care service should have access to rehabilitation services, plastic surgery, psychological services and nutritional services.

Healthcare professionals may need to discuss, agree and make special arrangements for disabled people and people who are housebound or living in care settings, to ensure equality of access to foot care assessments and treatments for people with diabetes.

Take into account any disabilities, including visual impairment, when planning and delivering care for people with diabetes.

Assessing the Risk of Developing a Diabetic Foot Problem

Frequency of Assessments

For children with diabetes who are under 12 years, give them, and their family members or carers (as appropriate), basic foot care advice.

For young people with diabetes who are 12 to 17 years, the paediatric care team or the transitional care team should assess the young person's feet as part of their annual assessment, and provide information about foot care. If a diabetic foot problem is found or suspected, the paediatric care team or the transitional care team should refer the young person to an appropriate specialist.

For adults with diabetes, assess their risk of developing a diabetic foot problem at the following times:

- When diabetes is diagnosed, and at least annually thereafter (see recommendation under "Managing the Risk of Developing a Diabetic Foot Problem" below)

- If any foot problems arise
- On any admission to hospital, and if there is any change in their status while they are in hospital

Assessing the Risk of Developing a Diabetic Foot Problem

When examining the feet of a person with diabetes, remove their shoes, socks, bandages and dressings, and examine both feet for evidence of the following risk factors:

- Neuropathy (use a 10 g monofilament as part of a foot sensory examination)
- Limb ischaemia (see the NGC summary of the NICE guideline Lower limb peripheral arterial disease: diagnosis and management)
- Ulceration
- Callus
- Infection and/or inflammation
- Deformity
- Gangrene
- Charcot arthropathy

Use ankle brachial pressure index in line with the NGC summary of the NICE guideline Lower limb peripheral arterial disease: diagnosis and management. Interpret results carefully in people with diabetes because calcified arteries may falsely elevate results.

Assess the person's current risk of developing a diabetic foot problem or needing an amputation using the following risk stratification:

- Low risk: no risk factors present
- Moderate risk: 1 risk factor present
- High risk: previous ulceration or amputation, on renal replacement therapy, or more than 1 risk factor present
- Active diabetic foot problem: ulceration, spreading infection, critical ischaemia, gangrene, suspicion of an acute Charcot arthropathy, or an unexplained hot, red, swollen foot with or without pain

Managing the Risk of Developing a Diabetic Foot Problem

For people who are at low risk of developing a diabetic foot problem, continue to carry out annual foot assessments, emphasise the importance of foot care, and advise them that they could progress to moderate or high risk.

Refer people who are at moderate or high risk of developing a diabetic foot problem to the foot protection service.

The foot protection service should assess newly referred people as follows:

- Within 2 to 4 weeks for people who are at high risk of developing a diabetic foot problem
- Within 6 to 8 weeks for people who are at moderate risk of developing a diabetic foot problem

For people at moderate or high risk of developing a diabetic foot problem, the foot protection service should:

- Assess the feet
- Give advice about, and provide, skin and nail care of the feet
- Assess the biomechanical status of the feet, including the need to provide specialist footwear and orthoses
- Assess the vascular status of the lower limbs
- Liaise with other healthcare professionals, for example, the person's general practitioner (GP), about the person's diabetes management and risk of cardiovascular disease

Depending on the person's risk of developing a diabetic foot problem, carry out reassessments at the following intervals:

- Annually for people who are at low risk
- Frequently (for example, every 3 to 6 months) for people who are at moderate risk
- More frequently (for example, every 1 to 2 months) for people who are at high risk, if there is no immediate concern
- Very frequently (for example, every 1 to 2 weeks) for people who are at high risk, if there is immediate concern

Consider more frequent reassessments for people who are at moderate or high risk, and for people who are unable to check their own feet.

People in hospital who are at moderate or high risk of developing a diabetic foot problem should be given a pressure redistribution device to offload heel pressure. On discharge they should be referred or notified to the foot protection service.

Patient Information about the Risk of Developing a Diabetic Foot Problem

Provide information and clear explanations to people with diabetes and/or their family members or carers (as appropriate) when diabetes is diagnosed, during assessments, and if problems arise. Information should be oral and written, and include the following:

- Basic foot care advice and the importance of foot care
- Foot emergencies and who to contact
- Footwear advice
- The person's current individual risk of developing a foot problem
- Information about diabetes and the importance of blood glucose control (also see the recommendation immediately below)

For guidance on education programmes and information about diabetes, see the education and information section in the NGC summary of the NICE guideline Type 1 diabetes in adults: diagnosis and management (NICE guideline NG17), the patient education section in the NICE guideline Type 2 diabetes in adults: management and the education and information for children and young people with type 1 diabetes and education and information for children and young people with type 2 diabetes sections in the NGC summary of the NICE guideline Diabetes (type 1 and type 2) in children and young people: diagnosis and management (NICE guideline NG18).

Diabetic Foot Problems

Referral

If a person has a limb-threatening or life-threatening diabetic foot problem, refer them immediately to acute services and inform the multidisciplinary foot care service (according to local protocols and pathways; also see "Care across All Settings" above), so they can be assessed and an individualised treatment plan put in place. Examples of limb-threatening and life-threatening diabetic foot problems include the following:

- Ulceration with fever or any signs of sepsis
- Ulceration with limb ischaemia (see the NGC summary of the NICE guideline Lower limb peripheral arterial disease: diagnosis and management)
- Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration)
- Gangrene (with or without ulceration)

For all other active diabetic foot problems, refer the person within 1 working day to the multidisciplinary foot care service or foot protection service (according to local protocols and pathways; also see "Care Across All Settings" above) for triage within 1 further working day.

Patient Information about Diabetic Foot Problems

Provide information and clear explanations as part of the individualised treatment plan for people with a diabetic foot problem. Information should be oral and written, and include the following:

- A clear explanation of the person's foot problem
- Pictures of diabetic foot problems
- Care of the other foot and leg
- Foot emergencies and who to contact
- Footwear advice
- Wound care
- Information about diabetes and the importance of blood glucose control (also see recommendation under "Patient Information about the Risk of Developing a Diabetic Foot Problem" above)

If a person presents with a diabetic foot problem, take into account that they may have an undiagnosed, increased risk of cardiovascular disease that may need further investigation and treatment. For guidance on the primary prevention of cardiovascular disease, see the NGC summary of the NICE guideline Lipid modification: cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease).

Diabetic Foot Ulcer

Investigation

If a person has a diabetic foot ulcer, assess and document the size, depth and position of the ulcer.

Use a standardised system to document the severity of the foot ulcer, such as the SINBAD (Site, Ischaemia, Neuropathy, Bacterial Infection,

Area and Depth) or the University of Texas classification system.

Do not use the Wagner classification system to assess the severity of a diabetic foot ulcer.

Treatment

Offer 1 or more of the following as standard care for treating diabetic foot ulcers:

- Offloading
- Control of foot infection
- Control of ischaemia
- Wound debridement
- Wound dressings

Offer non-removable casting to offload plantar neuropathic, non-ischaemic, uninfected forefoot and midfoot diabetic ulcers. Offer an alternative offloading device until casting can be provided.

In line with the NGC summary of the NICE guideline Pressure ulcers: prevention and management of pressure ulcers, use pressure-redistributing devices and strategies to minimise the risk of pressure ulcers developing.

When treating diabetic foot ulcers, debridement in hospital should only be done by healthcare professionals from the multidisciplinary foot care service, using the technique that best matches their specialist expertise and clinical experience, the site of the diabetic foot ulcer and the person's preference.

When treating diabetic foot ulcers, debridement in the community should only be done by healthcare professionals with the relevant training and skills, continuing the care described in the person's treatment plan.

Consider negative pressure wound therapy after surgical debridement for diabetic foot ulcers, on the advice of the multidisciplinary foot care service.

When deciding about wound dressings and offloading when treating diabetic foot ulcers, take into account the clinical assessment of the wound and the person's preference, and use devices and dressings with the lowest acquisition cost appropriate to the clinical circumstances.

Consider dermal or skin substitutes as an adjunct to standard care when treating diabetic foot ulcers, only when healing has not progressed and on the advice of the multidisciplinary foot care service.

Do not offer the following to treat diabetic foot ulcers, unless as part of a clinical trial:

- Electrical stimulation therapy, autologous platelet-rich plasma gel, regenerative wound matrices and dalteparin
- Growth factors (granulocyte colony-stimulating factor [G-CSF], platelet-derived growth factor [PDGF], epidermal growth factor [EGF] and transforming growth factor beta [TGF-β])
- Hyperbaric oxygen therapy

When deciding the frequency of follow-up as part of the treatment plan, take into account the overall health of the person with diabetes, how healing has progressed, and any deterioration.

Ensure that the frequency of monitoring set out in the person's individualised treatment plan is maintained whether the person with diabetes is being treated in hospital or in the community.

Diabetic Foot Infection

Investigation

If a diabetic foot infection is suspected and a wound is present, send a soft tissue or bone sample from the base of the debrided wound for microbiological examination. If this cannot be obtained, take a deep swab because it may provide useful information on the choice of antibiotic treatment.

Consider an X-ray of the person's affected foot (or feet) to determine the extent of the diabetic foot problem.

Think about osteomyelitis if the person with diabetes has a local infection, a deep foot wound or a chronic foot wound.

Be aware that osteomyelitis may be present in a person with diabetes despite normal inflammatory markers, X-rays or probe-to-bone testing.

If osteomyelitis is suspected in a person with diabetes but is not confirmed by initial X-ray, consider magnetic resonance imaging (MRI) to confirm the diagnosis.

Treatment

All hospital, primary care and community settings should have antibiotic guidelines covering the care pathway for managing diabetic foot infections that take into account local patterns of resistance.

Do not offer antibiotics to prevent diabetic foot infections.

Start antibiotic treatment for suspected diabetic foot infection as soon as possible. Take cultures and samples before, or as close as possible to, the start of antibiotic treatment.

Choose the antibiotic treatment based on the severity of the diabetic foot infection, the care setting, and the person's preferences, clinical situation and medical history and, if more than 1 regimen is appropriate, select the regimen with the lowest acquisition cost.

Decide the targeted antibiotic regimen for diabetic foot infections based on the clinical response to antibiotics and the results of the microbiological examination.

Do not offer tigecycline to treat diabetic foot infections unless other antibiotics are not suitable.

For mild diabetic foot infections, initially offer oral antibiotics with activity against gram-positive organisms.

Do not use prolonged antibiotic treatment (more than 14 days) for the treatment of mild soft tissue diabetic foot infections.

For moderate and severe diabetic foot infections, initially offer antibiotics with activity against gram-positive and gram-negative organisms, including anaerobic bacteria, as follows:

- Moderate infections: base the route of administration on the clinical situation and the choice of antibiotic
- Severe infections: start with intravenous antibiotics and then reassess, based on the clinical situation

Offer prolonged antibiotic treatment (usually 6 weeks) to people with diabetes and osteomyelitis, according to local protocols.

Charcot Arthropathy

Investigation

Be aware that if a person with diabetes fractures their foot or ankle, it may progress to Charcot arthropathy.

Suspect acute Charcot arthropathy if there is redness, warmth, swelling or deformity (in particular, when the skin is intact), especially in the presence of peripheral neuropathy or renal failure. Think about acute Charcot arthropathy even when deformity is not present or pain is not reported.

To confirm the diagnosis of acute Charcot arthropathy, refer the person within 1 working day to the multidisciplinary foot care service for triage within 1 further working day. Offer non-weight-bearing treatment until definitive treatment can be started by the multidisciplinary foot care service.

If acute Charcot arthropathy is suspected, arrange a weight-bearing X-ray of the affected foot and ankle. Consider an MRI if the X-ray is normal but Charcot arthropathy is still suspected.

Treatment

If the multidisciplinary foot care service suspects acute Charcot arthropathy, offer treatment with a non-removable offloading device. If a non-removable device is not advisable because of the clinical, or the person's, circumstances, consider treatment with a removable offloading device.

Do not offer bisphosphonates to treat acute Charcot arthropathy, unless as part of a clinical trial.

Monitor the treatment of acute Charcot arthropathy using clinical assessment. This should include measuring foot–skin temperature difference and taking serial X-rays until the acute Charcot arthropathy resolves. Acute Charcot arthropathy is likely to resolve when there is a sustained temperature difference of less than 2 degrees between both feet and when X-ray changes show no further progression.

People who have a foot deformity that may be the result of a previous Charcot arthropathy are at high risk of ulceration and should be cared for by the foot protection service.

Definitions

Strength of Recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group (GDG) makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the GDG is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

*Interventions That Must (or Must Not) Be Used*

The GDG usually uses 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally the GDG uses 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

*Interventions That Should (or Should Not) Be Used – a 'Strong' Recommendation*

The GDG uses 'offer' (and similar words such as 'refer' or 'advise') when confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. The GDG uses similar forms of words (for example, 'Do not offer…') when confident that an intervention will not be of benefit for most patients.

*Interventions That Could Be Used*

The GDG uses 'consider' when confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

*Recommendation Wording in Guideline Updates*

NICE began using this approach to denote the strength of recommendations in guidelines that started development after publication of the 2009 version of The guidelines manual (January 2009).

## Clinical Algorithm(s)

A National Institute for Health and Care Excellence (NICE) pathway titled "Foot care for people with diabetes" is available from the NICE Web site .

# Scope

## Disease/Condition(s)

Diabetic foot problems, including diabetic foot ulcer, diabetic foot infections, and Charcot arthropathy

## Guideline Category

Evaluation

Management

Prevention

Risk Assessment

Treatment

## Clinical Specialty

Endocrinology

Family Practice

Internal Medicine

Nursing

Pediatrics

Podiatry

## Intended Users

Advanced Practice Nurses

Dietitians

Hospitals

Nurses

Patients

Physician Assistants

Physicians

Podiatrists

## Guideline Objective(s)

To offer best practice advice on the care of adults, young people and children with type 1 or type 2 diabetes with, or at risk of developing, diabetic foot problems

## Target Population

Adults, young people and children with type 1 or type 2 diabetes

## Interventions and Practices Considered

Organisation of Care

1. Definition and composition of the foot protection team and the multidisciplinary foot care team
2. Indications for referral to the foot protection and multidisciplinary foot care teams

Risk Assessment/Evaluation/Prevention

1. Foot examination and risk classification
2. Prevention strategies for people with diabetes who are at risk of developing foot problems, including:
    - Frequency of review
    - Information, advice and education for adults, young people and children (including family members and carers, as appropriate) about self-monitoring and preventing foot problems
    - Footwear or foot orthoses
    - Skin and nail care
3. Assessment and diagnosis of foot problems (ulcers, soft tissue infections, osteomyelitis and gangrene) in people with diabetes

Management/Treatment

1. Management strategies for foot problems (ulcers, soft tissue infections, osteomyelitis or gangrene) resulting from diabetes, including:
    - Frequency of review
    - Information, advice and education for adults, young people and children (including family members and carers, as appropriate) about self-care and preventing further foot problems
    - Footwear or foot orthoses
    - Blood glucose management
2. Treatments for foot problems (ulcers, soft tissue infections, osteomyelitis or gangrene) resulting from diabetes, including:
    - Surgical or non-surgical debridement, wound dressings, off-loading (removal of weight bearing)
    - Antibiotic regimens and antimicrobial therapy for foot infection
    - Other adjunctive treatments, including dermal or skin substitutes, growth factors, hyperbaric oxygen therapy, bio-debridement, topical negative pressure therapy, electrical stimulation (most adjunctive treatments are not recommended routinely; see the "Major Recommendations" field)
3. Investigating orthopaedic and vascular complications and referring to specialist services (e.g., signs and symptoms of Charcot arthropathy, lower limb ischaemia)
4. Indications for referral to other specialist services
5. Diagnosis and management Charcot arthropathy

## Major Outcomes Considered

- Rates and extent of amputation (major or minor)
- Rates (and recurrent rates) of foot ulcerations, soft tissue infections, osteomyelitis and gangrene
- Healing rates of foot ulcers
- Health-related quality of life of people with diabetic foot problems (ideally this will include data from validated generic instruments such as the EQ-5D that are able to provide a single index value of health status [on a scale of 0 to 1]; generic health survey questionnaire data, such as from the Short Form 36, may also be appropriate)
- Rates of hospital admission and re-admission
- Length of hospital stay
- Mortality
- Adverse events of treatment
- Resource use and costs
- Patient experience of care

# Methodology

## Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the Internal Clinical Guidelines (ICG) Programme on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Search Strategies

The evidence reviews used to develop the guideline recommendations were underpinned by systematic literature searches, following the methods described in The guidelines manual (2012) (see the "Availability of Companion Documents" field). The aim of the systematic searches was to comprehensively identify the published evidence to answer the review questions developed by the Guideline Development Group (GDG) and the

ICG team.

The search strategies for the review questions were developed by the Information Services Team with advice from the ICG team. Structured questions were developed using the PICO (population, intervention, comparison, outcome) model and translated into search strategies using subject heading and free text terms. The strategies were run across a number of databases and date restrictions were included when requested by the ICG team.

The National Health Service Economic Evaluation Database (NHS EED) and the Health Economic Evaluations Database (HEED) were searched for economic evaluations. Search filters for economic evaluations and quality of life studies were used on bibliographic databases. Date restrictions were included when requested by the ICG team.

GDG members were also asked to alert the ICG team to any additional evidence, published, unpublished or in press, that met the inclusion criteria.

The searches were undertaken between July 2013 and February 2014. The re-run searches took place in August 2014.

Further details of the search strategies are provided in Appendix D in the full guideline appendices (see the "Availability of Companion Documents" field).

Systematic Review of Published Cost–Utility Analyses

A systematic literature search was conducted in order to identify published cost–utility analyses that provide evidence of the cost-effectiveness of the interventions in question.

Inclusion and Exclusion Criteria

The economic literature review aimed to identify economic evaluations in the form of cost–utility analyses exploring the costs and effects of preventative measures including information, advice and education about self-monitoring and preventing foot problems; appropriate footwear, provision of foot orthoses and skin and nail care. Reviewers also considered studies that examined the cost effectiveness of risk assessment strategies, and those that examined the utility of different lengths of follow-up.

Search Strategy

The search strategy was based on that used to identify clinical evidence for these questions, with the randomised controlled trial (RCT) filter removed and a standard economic filter applied (see Appendix D in the full guideline appendices).

## Number of Source Documents

Citations for included studies for each review question can be found in Section 5, References, in the full version of the guideline (see the "Availability of Companion Documents" field).

A list of excluded studies and reasons for exclusion for each review question can be found in Appendix E in the full guideline appendices (see the "Availability of Companion Documents" field).

## Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

Overall Quality of Outcome Evidence in Grading of Recommendations Assessment, Development and Evaluation (GRADE)

| Level | Description |
|---|---|
| High | Further research is very unlikely to change confidence in the estimate of effect. |
| Moderate | Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate. |

| Level | Description |
| --- | --- |
| Low | Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate. |
| Very Low | Any estimate of effect is very uncertain. |

## Methods Used to Analyze the Evidence

Meta-Analysis

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the Internal Clinical Guidelines (ICG) Programme on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Methods

Outcomes

The outcomes prioritised in the review questions reflect the treatment objectives in the prevention, recognition, diagnosis, treatment and management of diabetic foot problems such as rates of ulceration, infection, complications and amputation rates. Unless otherwise stated, the minimal important difference (MID) for dichotomous outcomes was defined as a relative risk reduction or an increase of 25% or more to be considered clinically important. If required, the minimum important difference for continuous outcomes could be decided by looking at appropriate published evidence or under agreement with the Guideline Development Group (GDG) following discussion within committee meetings.

Process

Data were extracted by 1 reviewer. A second reviewer checked a random 10% of sifted out titles and abstracts, and all excluded studies with the reason for exclusion, and all data extracted for the included studies.

Evidence Synthesis and Meta-analyses

Where possible, meta-analyses were conducted to combine the results of studies for each outcome. For continuous outcomes, where change from baseline data were reported in the trials and were accompanied by a measure of spread (for example standard deviation), these were extracted and used in the meta-analysis. Where measures of spread for change from baseline values were not reported, the corresponding values at study end were used and were combined with change from baseline values to produce summary estimates of effect. These studies were assessed to ensure that baseline values were balanced across the treatment groups; if there were significant differences at baseline these studies were not included in any meta-analysis and were reported separately.

Refer to Appendix H in the full guideline appendices (see the "Availability of Companion Documents" field) for additional details on the specific analyses performed.

Quality Assessment

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) was used to assess the quality of evidence for the selected outcomes as specified in The guidelines manual (2012) (see the "Availability of Companion Documents" field). Where randomised controlled trials (RCTs) are possible, these are initially rated as high quality and the quality of the evidence for each outcome was downgraded or not from this initial point. If non-RCT evidence was included for intervention-type systematic reviews then these are initially rated a low quality and the quality of the evidence for each outcome was downgraded or not from this point.

Refer to Table 1 in Section 3.1.4.1 of the full version of the guideline for the rationale for downgrading quality of evidence. See the "Rating Scheme for the Strength of the Evidence" field for definitions of final GRADE ratings.

Modified GRADE for Prognostic Evidence

GRADE has not been developed for use with prognostic studies; therefore, a modified approach was applied using the GRADE framework with prognostic studies. The same criteria (risk of bias, inconsistency, imprecision and indirectness) were used to downgrade the quality of evidence as outlined in Table 2 in Section 3.1.4.2 of the full version of the guideline.

Modified GRADE for Diagnostic Evidence

GRADE has not been developed for use with diagnostic studies; therefore, a modified approach was applied using the GRADE framework. Cohort studies within the non-modified GRADE approach start at the low quality level due to accepted inherent study design limitations. Within a modified approach it is acceptable to initially indicate a high quality level to this study type and to assess the quality of evidence from this point. The same criteria (risk of bias, inconsistency, imprecision and indirectness) were used to downgrade the quality of evidence as detailed in Table 3 in Section 3.1.4.3 of the full version of the guideline.

Health Economic Evidence

The economic evaluation aimed to assess the cost-effectiveness of providing custom orthotic footwear (shoes and inserts) to patients at low, moderate and high risk of developing foot ulcers. The analysis considered the cost perspective of the National Health Service/Personal Social Services (NHS/PSS) as per the NICE reference case.

Quality Appraisal

Studies that met the eligibility criteria were assessed using the quality appraisal criteria as outlined in The guidelines manual (2012).

Original Cost-Utility Model

Given the absence of relevant, high-quality evidence in the published literature, a *de novo* Markov model was developed to assess the cost effectiveness of providing custom orthotic footwear (shoes and inserts and education on their use) to patients at low, moderate and high risk of developing foot ulcers. No economic evaluation of risk assessment could be found in the existing literature, and the clinical evidence was insufficient to parameterise an analysis of risk assessment compared with some control measure. Therefore, the model assumes at the start that all patients receive a risk assessment by an appropriately trained professional. It was envisioned that the model would demonstrate the utility of risk assessment indirectly should it find that targeting patients at a particular risk level was cost effective compared with providing the intervention to all patients regardless of risk. Unfortunately, different lengths of screening interval could not be modelled because of a lack of clinical evidence in this area (see Section 4.5 in the full version of the guideline). Therefore the *de novo* model could not provide a health economic answer to this issue.

See Appendix J in the full guideline appendices for further details of the Markov model structure and the parameters used.

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the Internal Clinical Guidelines (ICG) Programme on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance and related appendices.

NICE commissioned the ICG team to develop this guideline. The team established a Guideline Development Group (GDG), which reviewed the evidence and developed the recommendations.

The methods and processes for developing NICE clinical guidelines are described in The guidelines manual (2012) (see the "Availability of Companion Documents" field).

The Remit

This is an update of Management of type 2 diabetes: prevention and management of foot problems (NICE clinical guideline 10, 2004) and a partial update (covering the recommendations on foot care only) of Type 1 diabetes: diagnosis and management of type 1 diabetes in children, young people and adults (NICE clinical guideline 15, 2004) and Diabetic foot problems: inpatient management (NICE clinical guideline 119, 2011). The update incorporated recommendations 1.1.1 and 1.1.8 to 1.1.10 on inpatient management of diabetic foot problems in adults from Diabetic foot problems: inpatient management (NICE clinical guideline 119, 2011). Recommendations 1.1.37 to 1.1.40 from Diabetic foot problems: inpatient

management (NICE clinical guideline 119, 2011) were also stood down as these recommendations have now been updated by Lower limb peripheral arterial disease: Diagnosis and management (NICE clinical guideline 147, 2012). The GDG also carried out an editorial review of all recommendations to ensure that they comply with NICE's duties under equalities legislation.

## Rating Scheme for the Strength of the Recommendations

Strength of Recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group (GDG) makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the GDG is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

Interventions That Must (or Must Not) Be Used

The GDG usually uses 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally the GDG uses 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

Interventions That Should (or Should Not) Be Used – a "Strong" Recommendation

The GDG uses 'offer' (and similar words such as 'refer' or 'advise') when confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. The GDG uses similar forms of words (for example, 'Do not offer…') when confident that an intervention will not be of benefit for most patients.

Interventions That Could Be Used

The GDG uses 'consider' when confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

Recommendation Wording in Guideline Updates

NICE began using this approach to denote the strength of recommendations in guidelines that started development after publication of the 2009 version of the guidelines manual (January 2009).

## Cost Analysis

The health economic evidence identified by the health economics systematic review was summarised for each review question in the full version of the guideline (see the "Availability of Companion Documents" field).

Conclusions of the Original Cost-Utility Analysis on Provision of Bespoke Orthotic Footwear

The analysis suggests that providing patients who are at moderate and high risk of ulceration with bespoke orthotic footwear is cost effective. Providing high-risk patients with this intervention is cost saving. In the base-case analysis, off-the-shelf orthotics were just cost effective at a threshold of £20,000 per quality-adjusted life-year (QALY), but were not considered cost effective in the probabilistic sensitivity analysis. The model was shown to be sensitive to the effect estimates and the cost of the intervention, with high-cost orthotics only considered cost effective for use in high-risk patients.

See Appendix J in the full guideline appendices (see the "Availability of Companion Documents" field) for a complete description of this analysis.

## Method of Guideline Validation

External Peer Review

Internal Peer Review

### Description of Method of Guideline Validation

The guideline was validated through two consultations.

1. The first draft of the guideline (the full guideline and the National Institute for Health and Care Excellence [NICE] guideline) were consulted with stakeholders and comments were considered by the Guideline Development Group (GDG).
2. The final consultation draft of the full guideline, the NICE guideline and the Information for the Public were submitted to stakeholders for final comments.

The final draft was submitted to the Guideline Review Panel for review prior to publication.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Improved care could prevent ulceration from developing into further complications such as infection, gangrene, amputation and death. Reducing the rates of these outcomes will also result in improved rates of hospital admission and resource use.

Refer to the "Trade-off between benefits and harms" sections in the full version of guideline (see the "Availability of Companion Documents" field) for additional details about benefits of specific interventions.

### Potential Harms

Potential harm as a result of offering management strategies could include having a direct adverse effect as a result of using the therapy or where use of the treatment is found to worsen or slow the progress of healing.

Refer to the "Trade-off between benefits and harms" sections in the full version of guideline document (see the "Availability of Companion Documents" field) for additional details about harms of specific interventions.

## Qualifying Statements

### Qualifying Statements

- This guidance represents the view of the National Institute for Health and Care Excellence (NICE), which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summaries of product characteristics of any drugs.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.
- For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision,

- See the "Person-centred care" section in the original guideline document for information about individual needs and preferences and transition of care.
- See the original guideline document for information on safeguarding children.

# Implementation of the Guideline

## Description of Implementation Strategy

Implementation tools and resources to help users put the guideline into practice are available (see also the "Availability of Companion Documents" field).

Key Priorities for Implementation

The following recommendations have been identified as priorities for implementation.

See "Implementation: getting started" in the original guideline document for information about putting the recommendations on dermoscopy, managing suboptimal vitamin D levels, sentinel lymph node biopsy and completion lymphadenectomy into practice.

Care within 24 Hours of a Person with Diabetic Foot Problems Being Admitted to Hospital, or the Detection of Diabetic Foot Problems (If the Person Is Already in Hospital)

Each hospital should have a care pathway for people with diabetic foot problems who need inpatient care. [2011]

Care Across All Settings

Commissioners and service providers should ensure that the following are in place:

- A foot protection service for preventing diabetic foot problems, and for treating and managing diabetic foot problems in the community.
- A multidisciplinary foot care service for managing diabetic foot problems in hospital and in the community that cannot be managed by the foot protection service. This may also be known as an interdisciplinary foot care service.
- Robust protocols and clear local pathways for the continued and integrated care of people across all settings, including emergency care and general practice. The protocols should set out the relationship between the foot protection service and the multidisciplinary foot care service.
- Regular reviews of treatment and patient outcomes, in line with the National Diabetes Foot Care Audit.

Assessing the Risk of Developing a Diabetic Foot Problem

For adults with diabetes, assess their risk of developing a diabetic foot problem at the following times:

- When diabetes is diagnosed, and at least annually thereafter
- If any foot problems arise
- On any admission to hospital, and if there is any change in their status while they are in hospital

When examining the feet of a person with diabetes, remove their shoes, socks, bandages and dressings, and examine both feet for evidence of the following risk factors:

- Neuropathy (use a 10 g monofilament as part of a foot sensory examination)
- Limb ischaemia (see the National Guideline Clearinghouse (NGC) summary of the NICE guideline Lower limb peripheral arterial disease: diagnosis and management)
- Ulceration
- Callus
- Infection and/or inflammation
- Deformity
- Gangrene
- Charcot arthropathy

Assess the person's current risk of developing a diabetic foot problem or needing an amputation using the following risk stratification:

- Low risk: no risk factors present

- Moderate risk: 1 risk factor present
- High risk: previous ulceration or amputation, on renal replacement therapy, or more than 1 risk factor present
- Active diabetic foot problem: ulceration, spreading infection, critical ischaemia, gangrene, suspicion of an acute Charcot arthropathy, or an unexplained hot, red, swollen foot with or without pain

Diabetic Foot Problems

If a person has a limb-threatening or life-threatening diabetic foot problem, refer them immediately to acute services and inform the multidisciplinary foot care service (according to local protocols and pathways), so they can be assessed and an individualised treatment plan put in place. Examples of limb-threatening and life-threatening diabetic foot problems include the following:

- Ulceration with fever or any signs of sepsis
- Ulceration with limb ischaemia (see the NGC summary of the NICE guideline Lower limb peripheral arterial disease: diagnosis and management)
- Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration)
- Gangrene (with or without ulceration)

For all other active diabetic foot problems, refer the person within 1 working day to the multidisciplinary foot care service or foot protection service (according to local protocols and pathways) for triage within 1 further working day.

Diabetic Foot Infection

All hospital, primary care and community settings should have antibiotic guidelines covering the care pathway for managing diabetic foot infections that take into account local patterns of resistance.

Charcot Arthropathy

Suspect acute Charcot arthropathy if there is redness, warmth, swelling or deformity (in particular, when the skin is intact), especially in the presence of peripheral neuropathy or renal failure. Think about acute Charcot arthropathy even when deformity is not present or pain is not reported.

To confirm the diagnosis of acute Charcot arthropathy, refer the person within 1 working day to the multidisciplinary foot care service for triage within 1 further working day. Offer non-weight-bearing treatment until definitive treatment can be started by the multidisciplinary foot care service.

## Implementation Tools

Clinical Algorithm

Mobile Device Resources

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Getting Better

Living with Illness

Staying Healthy

## IOM Domain

Effectiveness

Patient-centeredness

Timeliness

# Identifying Information and Availability

## Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Diabetic foot problems: prevention and management. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Aug 26. 47 p. (NICE guideline; no. 19).

## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2011 Mar (revised 2015 Aug 26)

## Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

## Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

## Guideline Committee

Guideline Development Group (GDG)

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## Financial Disclosures/Conflicts of Interest

Members of the Guideline Development Group (GDG) made declarations of interest; see Section 4.4 in the original guideline document. All other members of the Group stated that they had no interests to declare.

## Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Centre for Clinical Practice. Diabetic foot problems. Inpatient management of diabetic foot problems. London (UK): National Institute for Health and Clinical Excellence (NICE); 2011 Mar. 31 p. (Clinical guideline; no. 119).

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Available from the National Institute for Health and Care Excellence (NICE) Web site. Also available in ePub or eBook formats from the NICE Web site.

## Availability of Companion Documents

The following are available:

- Diabetic foot problems: prevention and management. Full guideline. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Aug. 282 p. (NICE guideline; no. 19). Available from the NICE Web site.
- Diabetic foot problems: prevention and management. Appendices. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Aug. (NICE guideline; no. 19). Available from the NICE Web site.
- Diabetic foot problems: prevention and management. Baseline assessment tool. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Aug. (NICE guideline; no. 19). Available from the NICE Web site.
- Diabetic foot problems: prevention and management. Costing report. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Aug. 17 p. (NICE guideline; no. 19). Available from the NICE Web site.
- Diabetic foot problems: prevention and management. Costing template. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Aug. (NICE guideline; no. 19). Available from the NICE Web site.
- The guidelines manual 2012. London (UK): National Institute for Health and Care Excellence (NICE); 2012 Nov. Available from the NICE Web site.

## Patient Resources

The following is available:

- Diabetic foot problems: prevention and management. Information for the public. London (UK): National Institute for Health and Care Excellence; 2015 Aug. (NICE guideline; no. 19). Available from the National Institute for Health and Care Excellence (NICE) Web site.

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